

Applicants: Allan Green et al.  
Serial No.: 09/837,751 Filed: April 18, 2001  
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**REMARKS**

Claims 109-146 were pending in the subject application. Applicants have hereinabove canceled claims 127-130 and 140-143, without prejudice. Accordingly, claims 109-126, 131-139 and 144-146 are currently pending in the subject application.

**December 22, 2004 Telephone Conference with Examiner**

Initially, applicants thank Examiner McElwain for the courtesy extended during the December 22, 2004 telephone conference with the undersigned. The Examiner's comments were most helpful in preparing this amendment, which applicants believe places the subject application in condition for allowance.

The rejections and objections set forth in the August 4, 2004 Final Office Action were discussed during the December 22, 2004 telephone conference. Specifically, during the December 22, 2004 telephone conference applicants agreed to cancel without prejudice withdrawn claims 127-130. Examiner McElwain during the conference also inquired as to applicants' intentions with respect to withdrawn claims 140-143. Upon further consideration, to expedite the allowance of the subject application, applicants have by this amendment also cancelled without prejudice withdrawn claims 140-143.

Applicants also pointed out to Examiner McElwain during the December 2, 2004 telephone conference the written description support for claims 109-126 and 131-139. In response, Examiner McElwain agreed that Table 10 on page 111 does provide written description support for the specific percentages ranges recited in claims 109-126 and 131-139.

Finally, Examiner McElwain clarified during the December 22, 2004 telephone conference that the enablement rejection of claims 109-

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126, 131-139 and 144-146 is questioning whether one skilled in the art would know *which portions* of the recited *ghFAD2-1* gene to target, e.g. with an antisense molecule, in order to specifically reduce delta-12 fatty acid desaturase activity. Examiner McElwain acknowledged that as of applicants' April 18, 2000 filing date, one skilled in the art would know *how* to target a gene to reduce its expression once the complete sequence of the gene has been identified. Thus, the Examiner's remaining question is whether one skilled in the art would know *which portions* of the gene to target given that the *ghFAD2-1* gene recited in applicants' claims is one member of a class of genes with sequence similarity.

Applicants appreciate the Examiner's thoughtful inquiry and point out that their specification provides the answer.

Page 39 lines 4-10 of applicants' disclosure describes the preferred degree of identity of the fragments for use in applicants' invention. Thus, as the Examiner pointed out, one skilled in the art would understand that the optimal gene silencing construct for specific silencing would have the maximal degree of identity with the gene to be silenced and be unique for that gene, while having minimal identify with another gene. Applicants' disclosure on page 39, lines 12-26, then proceeds to provide a description of how to compare and obtain percentage similarity between any two or more sequences, specifically referencing the widely used, "GAP program, which utilizes the algorithm of Needleman and Wunsch (1970)."

Turning to the specifics of the *ghFAD2-1* gene, page 85 of applicants' disclosure describes the relationship with its related gene. As noted in applicants' disclosure, the related gene, the *ghFAD2-2* gene, is divergent from *ghFAD2-1* in so far as

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it possesses unique 5'- and 3'-UTRs. Applicants' disclosure proceeds to describe how applicants' gene specific probes were, therefore, based on unique 3'-UTR sequences of *ghFAD2-1* and *ghFAD2-2* and were used in Southern and Northern blot analyses. Clearly, the regions of *ghFAD2-1* to be preferred for gene specific effect are described in applicants' specification. Indeed, the application of this knowledge was exemplified on page 93, beginning on line 4, and in Examples 16 and 17 on pages 109-121, where a 92 nucleotide region from the 5'-UTR, specific for *ghFAD2-1*, was used.

Having answered the Examiner's inquiry, applicants wish to also point out that the knowledge of which portions are unique in the *ghFAD2-1* gene is not critical. That is, as long as expression of the *ghFAD2-1* is reduced in the cotton plant, applicants' claimed result of the increased oleic acid content will be achieved. Whether the related gene, *ghFAD2-2*, might also be silenced is of no consequence. This conclusion is supported by actual experimentation as indicated in applicants' disclosure on page 113, line 31 to page 114, line 1: "Since similar results were obtained using different inverted repeat constructs, the modulation of fatty acid content obtained using inverted repeat sequences is not dependent on the precise nature of the inverted repeat in the gene construct".

Accordingly, applicants believe the foregoing resolves the sole remaining basis for the enablement rejection of claims 109-126, 131-139 and 144-146. Specifically, as discussed above, applicants' disclosure clearly sets forth *which portions* of the *ghFAD2-1* gene are preferable to target, and in any event, shows that targeting any portion of the *ghFAD2-1* gene results in applicants' claimed process.

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Applicants now turn to the grounds of rejection and objection set forth in the August 4, 2004 final Office Action, all of which have already been addressed during the December 22, 2004 telephone conference with the Examiner.

### **Election/Restrictions**

The Examiner maintained that claims 127-130 and 140-143 are drawn to a non-elected invention.

In response, as noted above and to expedite the allowance of this application, applicants have canceled claims 127-130 and 140-143 without prejudice to applicants' right to pursue the subject matter of these claims in a continuation application.

### **Rejection under 35 U.S.C. § 112, first paragraph - claims 109-126 and 131-139**

In Section 2 of the August 4, 2004 final Office Action, the Examiner rejected claims 109-126 and 131-139 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably enable one skilled in the relevant art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner alleged that the claims are drawn to plants comprising specific levels of certain fatty acids, 58.5%, 66% or 68.9% oleic acid, but applicants have not indicated where in the specification or the originally filed claims there is support for these specific percentages of oleic acid.

In response, as noted above and acknowledged by the Examiner, Table 10 on page 111 of applicants' disclosure provides the written description support for the specific levels, i.e. for 58.5%, 66% and 68.9% oleic acid. Accordingly, this rejection is moot.

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**Rejection under 35 U.S.C. § 112, first paragraph**

**- claims 109-126 and 131-139 and 144-146**

In Section 3 of the August 4, 2004 final Office Action, the Examiner rejected claims 109-126, 131-139 and 144-146 under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner alleged that the specification, while being enabling for a method of decreasing expression of a delta-12 fatty acid desaturase by transforming a cotton plant with a construct comprising either a full length delta-12 fatty acid desaturase gene in antisense or with a construct comprising inverted repeats of a delta-12 fatty acid desaturase gene that are 850 bp and optionally with a 92 intervening sequence, as well as the transgenic cotton plants and seeds produced by said method, does not reasonably provide enablement for the same method wherein the construct merely comprises a 20 nucleotide fragment of a delta-12 desaturase gene, as stated in the last office action for claims 62-65, 67-77, 79-85 and 101-108.

In response, as clarified during the December 22, 2004 telephone conference with the Examiner, based on applicants' April 18, 2000 filing date the issue of contention is not whether one skilled in the art would know how to target a known gene to reduce its expression, but rather whether one skilled in the art would know *which portions* of the gene to target given that the *ghFAD2-1* gene recited in applicants' claims is one member of a class of genes with sequence similarity.

As detailed above, applicants' have clearly disclosed *which portions* of the *ghFAD2-1* gene is preferable to target, and in any event, shows that targeting any portion of the *ghFAD2-1* gene results in applicants' claimed process.

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Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 109-126, 131-139 and 144-146 under 35 U.S.C. § 112, first paragraph.

### **Conclusion**

In view of the amendments and remarks hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the rejections and objection set forth in the August 4, 2004 Final Office Action and earnestly solicit allowance of pending claims 109-126, 131-139 and 144-146.

### **INFORMATION DISCLOSURE STATEMENT**

In accordance with their duty of disclosure under 37 C.F.R. § 1.56, applicants direct the Examiner's attention to the following documents which are listed on the Form PTO-1449 attached hereto as **Exhibit A** and also listed below.

This Information Disclosure Statement is being filed after the issuance of a Final Office Action. According to 37 C.F.R. § 1.97(d) documents submitted with this Information Disclosure Statement shall be considered if accompanied by the fee set forth in 37 C.F.R. § 1.17(p) and a statement under 37 C.F.R. § 1.97(e).

The required fee set forth in 37 C.F.R. § 1.17(p) is ONE HUNDRED AND EIGHTY DOLLARS (\$180.00) and a check for this amount is enclosed.

Pursuant to 37 C.F.R. § 1.97(e)(2), the undersigned states that documents 1-10 listed below were not cited in a communication from a foreign patent office in a counterpart application, and, to the knowledge of the undersigned after making reasonable inquiry, were not known to any individual designated in 37 C.F.R. § 1.56(c) more than three (3) months prior to the filing of this

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Information Disclosure Statement. Specifically, items 1-10 were cited in a November 25, 2004 Supplementary European Search Report in the European counterpart of the subject application, EP 01 92 3393, which is within three months of the date of filing this Information Disclosure Statement.

1. U.S. Patent 5,597,718, issued January 28, 1997, to Paul Umbeck et al. (**Exhibit 1**);
2. PCT International Publication No. WO 94/11516, published May 26, 1994 (**Exhibit 2**);
3. Budziszewski et al., "Uses of Biotechnology In Modifying Plant Lipids", Lipids, Champaign, IL, Vol. 31, No. 6, pages 557-569, (1996) (**Exhibit 3**);
4. Cartea et al., "Comparison of Sense And Antisense Methodologies For Modifying The Fatty Acid Composition of Arabidopsis Thaliana Oilseed", Plant Science, Limerick, IE, Vol. 136, No. 2, pages 181-194, (1998) (**Exhibit 4**);
5. Drew et al., "RNA Hairpin Loops repress Protein Synthesis More Strongly than Hammerhead Ribozymes", European Journal of Biochemistry, Vol. 226, No. 1, pages 260-273, (November 1999) (**Exhibit 5**);
6. Hisamatsu et al., "Efficiency of the Hairpin Ribozyme on the Inhibition of Gene Expression", Plant Physiology, Vol. 114, No. 3 Suppl., page 246, (1997) (**Exhibit 6**);
7. Knutzon et al., "Modification of Brassica Seed Oil by Antisense Expression of a Steraroyl-Acyl Carrier Protein Desaturase Gene", Proceedings of The National Academy of

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Sciences of USA, National Academy of Science, Washington,  
US, Vol. 89, pages 2624-2628, (April 1992) (**Exhibit 7**);

8. Smith et al., "Total Silencing by Intron-Spliced Hairpin RNAs", Nature, Macmillan Journals Ltd. London, GB, Vol. 407, No. 6802, pages 319-320, (September 2000) (**Exhibit 8**);
9. Toepfer et al., "Modification of Plant Lipid Synthesis", Science, American Association For the Advancement of Science, US, Vol. 268, pages 681-685, (May 5, 1995) (**Exhibit 9**); and
10. November 25, 2004 Supplementary European Search Report from the counterpart European application, EP 01 92 3393 (**Exhibit 10**).



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**REVOCATION OF POWER OF ATTORNEY,  
APPOINTMENT OF NEW ATTORNEY  
AND NOTICE OF NEW CORRESPONDENCE ADDRESS**

Applicants have previously submitted with their May 7, 2004 Amendment a Revocation of Power of Attorney, Appointment of New Attorney And Notice of New Correspondence Address. However, applicants note that as of the filing of this Amendment, the correspondence address has not been changed. Accordingly, applicants again attach a Copy of the Revocation of Power of Attorney, Appointment of New Attorney And Notice of New Correspondence Address as **Exhibit B** hereto. As requested in the attached document, please forward all future correspondence in connection with the subject application to:

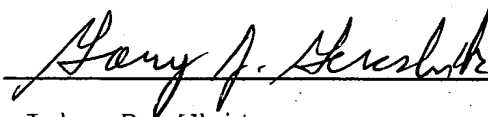
John P. White  
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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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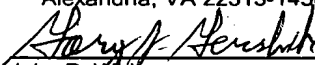
No fee, other than the enclosed \$1,020.00 fee for a three-month extension of time and the \$180.00 fee for an Information Disclosure Statement is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents, P.O. Box 1450  
Alexandria, VA 22313-1450.

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